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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/932,302	08/17/2001	Bertha K. Madras	56,007-CIP (70207)	5385

21874 7590 04/08/2004
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EXAMINER

HARTLEY, MICHAEL G

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 04/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/932,302

Applicant(s)

MADRAS ET AL.

Examiner

Michael G. Hartley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 November 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4,5,14-17,27 and 29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4, 5, 14-17, 27 and 29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>12/15/03</u> | 6) <input type="checkbox"/> Other: _____ |

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Response to Amendment

The amendment filed 11/28/2003 has been entered. Claims 1, 2, 4, 5, 10, 14-17, 27 and 29 are now pending

Response to Arguments

Applicant's arguments with respect to claims 1, 2, 4, 5, 10, 14-17, 27 and 29 have been considered but are moot in view of the following new ground(s) of rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 4, 5, 14-17, 27 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuhar (US 6,531,483) in view of Davies (US 5,760,055) and DiNinno (US 5,621,133) and Baker (US 5,874,090) and Murray (WO 99/10359), or Bell (US 5,902,797).

Kuhar discloses methods of diagnostic imaging comprising administering a dopamine transporter ligand (i.e., a radiolabeled tropane compound) and performing imaging thereof, see columns 1-2. The tropane compounds may be labeled with various nuclides for detection by PET or SPECT, including, ¹²³I, see column 2. Kuhar teaches that the methods are for detection of attention deficient disorders, see column 2, lines 24-29. Diagnostic methods are disclosed in columns 7+, which would include the use of controls, etc. to determine the binding to the dopamine transporter. The brain as a whole is imaged which would encompass the various parts thereof set forth in the claims.

Kuhar discloses diagnosing "attention deficit disorder" (ADD) but fails to specifically teach attention deficit hyperactivity disorder" (ADHD) as claimed. However, in the art, these terms (ADD and

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ADHD) are used interchangeably to encompass each other and/or are known in the art to be related disorders, as shown by the cited references below.

Davies teaches that the term ADD is commonly used to define attention deficit hyperactivity disorder (ADHD), see the paragraph bridging columns 1-2 and that ADHD is associated with dopamine, see columns 1-2.

DiNinno teaches that the term "attention deficit disorder" (i.e., as recited by Kuhar) encompasses disorders with hyperactivity (ADHD), see column 19, lines 50-59 and that these disorders are associated with dopamine, see column 1.

Baker teaches that ADHD encompasses "attention deficit disorder" (i.e., as recited by Kuhar).

Murray teaches that ADD (attention deficit disorder) includes ADHD, see page 1 and claims 1-2.

Bell teaches that ADD and ADHD are related in that the same treatment (RITALIN) is used to treat both conditions in an equivalent manner, see column 1.

It would have been obvious to one of ordinary skill in the art to diagnose ADHD given the teaching of diagnosing "attention deficit disorder" by Kuhar because the five references cited above (Davies, DiNinno, Baker, Murray and Bell) clearly shown the interchangeable use of these terms and/or the strong relationship between ADD and ADHD in the art, as a whole. For example, Davies teaches that ADHD is known as ADD or attention deficit disorder, while DiNinno and Murray teach that the term ADD or "attention deficit disorder" encompasses ADHD, while Baker teaches that ADHD encompasses ADD. Bell further shows that the conditions are known to be related, as the same therapy is used for both conditions. One of ordinary skill in the art would have been motivated to employ the teaching of diagnosing "attention deficit disorder" to all types of "attention deficit disorder" known in the art, which clearly is known to encompass ADHD (as shown by Davies, DiNinno, Baker, Murray and/or Bell) to gain the entire advantage taught to one of ordinary skill in the art by the methods disclosed by Kuhar

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kuhar (US 6,531,483) in view of Davies (US 5,760,055) and DiNinno (US 5,621,133) and Baker (US 5,874,090) and Murray (WO

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99/10359), or Bell (US 5,902,797), as applied to claims 1, 2, 4, 5, 14-17, 27 and 29 above, and further in view of Elmaleh (US 5,493,026).

Kuhar discloses methods of diagnostic imaging of attention deficit disorders comprising administering a radiolabeled tropane compound and performing imaging thereof, as set forth above.

Kuhar fails to specifically disclose the use of applicant's elected dopamine receptor ligand, ^{123}I -altropane. However, ^{123}I -altropane is a known dopamine transporter ligand which is safe and effective for diagnostic imaging, as shown by Elmaleh.

Elmaleh teaches ^{123}I -altropane is an especially effective dopamine transporter ligand which can be used for diagnostic methods using PET or SPECT, see columns 2 and figure 3.

It would have been obvious to one of ordinary skill in the art to substitute ^{123}I -altropane for the dopamine transporter ligand in the method of screening for attention deficit disorders disclosed by Kuhar because Kuhar teaches that various tropane compounds may be employed, and Elmaleh teaches that ^{123}I -altropane is an especially useful dopamine transporter ligand for diagnostic methods involving dopamine transporter using radioimaging methods.

Response to Arguments

Applicant's arguments filed 11/28/2003 have been fully considered but they are not persuasive.

Applicant asserts that in contrast to Kuhar, the methods of the present invention bind directly to dopamine transporters and are not necessarily associated with cocaine receptors.

This is not found persuasive because the claims do not exclude the dopamine transporter ligands disclosed by Kuhar, in fact, the specification teaches that any dopamine transporter ligand can be used, and Kuhar discloses such ligands.

Applicant asserts that Kuhar fails to teach ADHD and only teaches ADD and that there is a difference in the art as shown by related literature provided by applicant.

While the provided literature does show some differences between ADD and ADHD, the art as a whole uses the terms interchangeably and shows that attention deficit disorder (as recited by Kuhar) encompasses ADHD. The art as a whole not only provides a close association between ADD and ADHD

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but also an interchangeable use of these terms, therefore, providing a teaching that the ADD as taught by Kuhar would include, or at least, would also be applicable to ADHD.

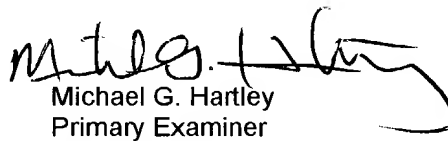
Conclusion

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael G. Hartley whose telephone number is (571) 272-0616. The examiner can normally be reached on M-F, 7:30-5, off alternative Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Michael G. Hartley
Primary Examiner
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4/5/2004